

**IN THE UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF NEBRASKA**

<p>JAMES HAN, As Special Administrator for the Estate of YOUNG HAN, Deceased,</p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p>RED OAK HEALTH SERVICES, INC. d/b/a HILLCREST HEALTH & REHAB, HILLCREST HEALTH SYSTEMS, INC. d/b/a HILLCREST HEALTH SERVICES, HILLCREST OPERATING VENTURES, LLC, RELYCARE PARTNERS, LLC d/b/a RELYCARE LTC PHARMACY BELLEVUE, YOUR HOMETOWN PHARMACY INC. d/b/a RELYCARE LTC PHARMACY BELLEVUE, OSIE, INC. d/b/a YOUR HOMETOWN PHARMACY, AND JOHN DOES 1-2,</p> <p style="text-align: center;">Defendants.</p>	<p>CASE NO.:</p> <p>JUDGE:</p> <p style="text-align: center;"><u>NOTICE OF REMOVAL</u></p> <p style="text-align: center;"><i>Removal from District Court of Sarpy County, Nebraska</i></p>
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COMES NOW Defendants Red Oak Health Services, Inc. d/b/a Hillcrest Health & Rehab; Hillcrest Health Systems, Inc. d/b/a Hillcrest Health Services, and Hillcrest Operating Ventures, LCC (herein “Removing Defendants”), by and through their attorneys, Pansing Hogan Ernst & Bachman, LLP, and hereby remove this action from the District Court of Sarpy County, Nebraska to the United States District Court for District of Nebraska, reserving all defenses and reserving all objections to venue based on 42 U.S.C. § 247d-6d(e)(1), pursuant to 28 U.S.C. §§ 1331, 1367, 1441, 1442, and 1446, and 42 U.S.C. § 247d-6d(e)(1), on the following grounds:

I. STATEMENT OF THE CASE

1. This action was commenced with the filing of a Summons and Complaint, in the District Court of Sarpy County, Nebraska on or about May 29, 2022. **Exhibit A.**

2. Upon information and belief, the Hillcrest Defendants were served on or about June 6, 2022. **Exhibit B.**

3. On July 6, 2022, Plaintiff and the Hillcrest Defendants entered into a stipulation extending their time to respond to the Complaint until July 20, 2022. **Exhibit C.** Accordingly, this Notice of Removal is timely. 28 U.S.C. § 1446(b).

4. Co-defendants RelyCare Partners, LLC d/b/a RelyCare LTC Pharmacy Bellevue; Your Hometown Pharmacy Inc. d/b/a RelyCare LTC Pharmacy Bellevue; and Osie, Inc. d/b/a Your Hometown Pharmacy consent to Removal to federal court.

5. This action arises out of the administration of the Moderna COVID-19 vaccine to YOUNG HAN (herein “Decedent”), an alleged resident of Hillcrest Health & Rehab (herein “Hillcrest”) between January 11, 2021 and March 11, 2021, allegedly causing death on March 16, 2021. **Exhibit A**, ¶ 4. Plaintiff alleges that each of the Hillcrest Defendants owned and operated, managed, or provided consulting services to a skilled nursing facility located at 1702 Hillcrest Drive, Bellevue, Sarpy County. *Id.* at ¶ 5(c), (d), ¶ 6(c), (d), ¶ 7(c), (d).

6. Plaintiff alleges that Hillcrest, and all of the Hillcrest Defendants, collectively (via their employees and agents), administered two doses of the Moderna COVID-19 vaccine to Decedent on February 3, 2021, and March 11, 2021. *Id.* at ¶ 5(f), ¶ 6(g), ¶ 7(h). Plaintiff also alleges that Defendants RelyCare Partners, LLC, Your Hometown Pharmacy, Inc., and Osie, Inc., (herein, “RelyCare Defendants”) administered three doses of the vaccine, on January 11, 2021, February 3, 2021, and March 11, 2021. *Id.* at ¶ 8(f), (g), ¶ 9(f), (g), ¶ 10(f), (g). Plaintiff

alleges, in effect, that the Hillcrest Defendants contracted with the RelyCare Defendants to provide COVID-19 vaccines to residents of Hilcrest. *Id.* at ¶ 20.

7. Plaintiff alleges that after the Decedent received a first dose of the Moderna vaccine on January 11, 2021, he was transferred from the “Hillcrest Millard” facility to the “Hillcrest Health & Rehab Skilled Nursing” (*id.* at ¶ 24); that when he received a second dose of the vaccine on February 3, 2021, it was too close in time to the first dose (i.e., less than 28 days) as per unspecified CDC guidelines (*id.* at ¶¶ 26-29); that neither Decedent nor his Healthcare Power of Attorney provided informed consent for the second dose (*id.* at ¶¶ 30-33); that Decedent became very ill but ultimately recovered within two weeks (*id.* at ¶ 35); that Decedent received a third dose of the vaccine on March 11, 2021, against unspecified CDC guidelines (*id.* at ¶¶ 36-39); that neither Decedent nor his Healthcare Power of Attorney provided informed consent for the third dose (*id.* at ¶¶ 40-46); and that Decedent became ill, with high fever, respiratory distress, extreme fatigue, and nausea, aspirated, suffered aspiration pneumonia, and ultimately died on March 16, 2021 (*id.* at 47-53).

8. These allegations place directly into issue the Hillcrest Defendant’s use and administration of covered countermeasures for the purpose of preventing, treating, diagnosing, and/or mitigating the spread of COVID-19, and the harms stemming therefrom, within the meaning of the Public Readiness and Emergency Preparedness (“PREP”) Act, 42 U.S.C. §§ 247d-6d(d), 247d-6e. Therefore, Plaintiff asserts a “claim for loss” for which federal law provides the exclusive cause of action available. *See* § 247d-6d(a)(1), (d)(1).

II. PROCEDURAL REQUIREMENTS

9. This notice is filed on behalf of the Hillcrest Defendants in the above-styled case. This Notice of Removal is being filed with the explicit consent of all co-defendants who, upon information and belief, have been served to date, pursuant to 28 U.S.C. § 1446(b)(2)(A)].

10. Concurrent with the filing of this Notice or promptly thereafter, this Notice of Removal is being served on all other parties pursuant to 28 U.S.C. § 1446(d).

11. Pursuant to 28 U.S.C. § 1446(a), copies of all state court documents served upon or provided to Defendants are attached as follows:

Exhibit	Date of Filing	Description
A	May 29, 2022	Summons and Complaint
B	June 6, 2022	Proof of Service
C	July 5, 2022	Stipulation Extending Time to Appear

12. As of the date this Notice of Removal is being filed, there have been no orders issued by the state court.

13. Removal to this venue is proper because the District Court of Sarpy County, Nebraska, lies within the jurisdictional boundary of United States District Court for the District of Nebraska. However, the Removing Defendants reserve all rights to contest venue as improper under 42 U.S.C. § 247d-6d(e)(1).

III. ARGUMENT AND CITATION TO AUTHORITY

A. FEDERAL QUESTION JURISDICTION UNDER 28 U.S.C. §§ 1331, 1441(a)

14. This case is removable under 28 U.S.C. § 1441(a) on the basis of “original jurisdiction” because Plaintiff’s Complaint asserts a claim that falls within the purview of the PREP Act and the Declaration Under the Public Readiness and Emergency Preparedness Act for

Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020), *amended by* 85 Fed. Reg. 21012 (Apr. 15, 2020), 85 Fed. Reg. 35100 (June 8, 2020), 85 Fed. Reg. 52136 (Aug. 24, 2020), 85 Fed. Reg. 79190 (Dec. 9, 2020), 86 Fed. Reg. 7872 (Feb. 2, 2021), 86 Fed. Reg. 9516 (Feb. 16, 2021) *as corrected by* 86 Fed. Reg. 10588 (Feb. 22, 2021), *and* 86 Fed. Reg. 14462 (Mar. 16, 2021), 86 Fed. Reg. 41977 (Aug 4, 2021), 87 Fed. Reg. 982 (Jan. 7, 2022) (herein “the Declaration”). Therefore, the Complaint asserts a claim “arising under” federal law within the meaning of § 1331.

15. Although the Complaint does not, on its face, rely upon any provision of federal law, federal question jurisdiction is proper under the doctrine of “complete preemption.” The PREP Act meets the criteria for complete preemption by broadly preempting all state law claims within its ambit and by providing an exclusive set of federal remedies, including, but not limited to immunity from suit.

16. Federal question jurisdiction is also proper under the “substantial federal question” doctrine because the Complaint sets forth causes of action that necessarily turn on disputed questions of federal law and removal would further the congressionally-mandated division of state and federal interests under the PREP Act. Pursuant to its authority under the PREP Act, the United States Department of Health and Human Services (“HHS”) has declared that any claim falling within the PREP Act presents a “substantial federal question” and is therefore removable. *See* 85 Fed. Reg. 79190.

17. Here, Plaintiff’s Complaint falls under the PREP Act because it asserts claims for loss “caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” Therefore, federal question jurisdiction exists over the claim.

i. **The Doctrine of “Complete Preemption” Applies to Any Claim Preempted Under the PREP Act Because the PREP Act (1) Expressly Preempts State Law Claims for Loss, and (2) Provides an Exclusive Set of Federal Remedies**

18. Plaintiff’s claim is removable under federal question jurisdiction because the PREP Act simultaneously preempts this claim and provides an exclusive federal cause of action and an exclusive administrative remedy for all tort claims arising out of or relating to the administration or use of a covered countermeasure.

19. The issue of whether federal question jurisdiction exists when a Complaint asserts a claim in state law is addressed in *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1 (2003). The Court explained:

[A] state claim may be removed to federal court ... when a federal statute wholly displaces the state-law cause of action through **complete pre-emption**. When the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law. In the two categories of cases where this Court has found complete pre-emption ... the federal statutes at issue **provided the exclusive cause of action** for the claim asserted and also **set forth procedures and remedies governing that cause of action**.

Id. at 8 (emphasis supplied; internal citations and footnotes omitted).

20. The doctrine of complete preemption is distinguishable from the various types of “ordinary” (or “defensive”) preemption—such as express, field, and conflict preemption—in that it provides federal removal jurisdiction. *See, e.g., Elam v. Kansas City Southern Ry. Co.*, 635 F.3d 796, 803 (5th Cir. 2011); *Devon Energy Prod. Co. v. Mosaic Potash Carlsbad, Inc.*, 693 F.3d 1195, 1204 (10th Cir. 2012); *Retail Prop. Tr. v. United Broth. of Carpenters and Joiners of Am.*, 768 F.3d 938, 948-49 (9th Cir. 2014). It is also distinguishable from situations where Congress expressly provides for removal jurisdiction within the preemptive federal statute. *See Beneficial*, 539 U.S. at 8 (discussing the Price-Anderson Act, which contained an express removal provision). The focus of the complete preemption analysis is on the framework of the

relevant federal statute as an indication of an implicit congressional intent to permit removal. *See id.* at 8.

21. Circuit and district courts considering the issue have found “complete preemption” where a federal statute (1) expressly preempts state law and (2) creates an exclusive federal remedy for preempted state claims. *See, e.g., In re WTC Disaster Site*, 414 F.3d 352, 380 (2d Cir. 2005); *Spear Marketing, Inc. v. Bancorp South Bank*, 791 F.3d 586 (5th Cir. 2015); *Nott v. Aetna U.S. Healthcare, Inc.*, 303 F.Supp.2d 565 (E.D.Pa. 2004).

22. The PREP Act satisfies both prongs of this analysis. First, the PREP Act preempts state law to the extent that it would deprive an individual or entity of the immunity it confers. Under 42 U.S.C. § 247d-6d(a)(1), a “covered person” is afforded broad immunity “from suit and liability under Federal and State law” for “all claims for loss caused by, arising out of, relating to, or resulting from” the “administration” or “use” of a “covered countermeasure” if the Secretary of the Department of Health and Human Services issues a declaration to that effect—which it has. Moreover, under Section 247d-6d(b)(8), state law that “is different from, or in conflict with, any requirement applicable under this section and relates to ... the administration by qualified persons of the covered countermeasure” is expressly preempted. This language would include enforcement of common law through the a state tort system. Therefore, under the Declaration, the PREP Act broadly preempts a wide array of state law claims.

23. Second, the PREP Act establishes an exclusive federal cause of action for any claim preempted, and also establishes the procedures applicable to such actions. Under 42 U.S.C. § 247d-6d(d)(1) “the sole exception to the immunity from suit and liability of covered persons ... shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct.” Claims for “willful misconduct” are

subject to several heightened pleading requirements. § 247d-6d(e)(1)-(4). Moreover, any action for “willful misconduct” “shall be filed and maintained only in the United States District Court for the District of Columbia,” and must be brought before a three-judge panel. § 247d-6d(e)(1), (e)(5). The PREP Act also establishes a host of other procedural requirements for such claims, including limitations on damages and limited discovery rights. *See generally*, § 247d-6d(e).

24. On January 8, 2021, HHS issued an Advisory Opinion expressly stating that the PREP Act triggers the doctrine of “complete preemption,” including in claims of negligent infection control within an adult care facility. HHS, Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision (Jan. 8, 2021).¹

25. Since the onset of the COVID-19 pandemic, several district courts have addressed whether the PREP Act is the type of statute that triggers complete preemption. To date, two district courts have recognized that the PREP Act triggers complete preemption. *See Garcia v. Welltower OpCo Group, LLC*, No. 8:20-cv-02250 (C.D. Cal. Feb. 10, 2021); *Rachel v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-334, at *N.3 (W.D.L.A. Apr. 30, 2021).

26. In *Rachal*, the court concluded that the PREP Act satisfied all criteria for complete preemption because it (1) contained a civil enforcement provision that replaces and protects an analogous area of state law; (2) contained a specific jurisdictional grant to the federal courts to enforce the same; and (3) contained a clear congressional intent that such jurisdiction would be exclusive. It also found the PREP Act particularly analogous to the Air Transportation Safety and System Stabilization Act because both statutes (1) create an administrative no-fault compensation fund; (2) provide broad immunity from suit for certain entities/individuals; (3)

¹ Available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf>.

create an exclusive federal cause of action for certain residual claims; and (4) confer exclusive jurisdiction over such causes of action unto a specified federal venue. *Rachal*, at n. 3, citing *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005).

27. In contrast to *Garcia* and *Rachal*, other courts have granted remand of cases removed under the PREP Act. Defendant submits that these remands were made in error. Some decisions pre-dated the Fourth Amendment to the Declaration and Advisory Opinion 21-01 and were predicated on a false interpretation of the PREP Act that it does not cover claims of inaction surrounding covered countermeasures. *See, e.g., Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F.Supp.3d 518 (D.N.J. 2020), *aff'd*, 16 F.4th 393 (3d Cir. 2022); *Lutz v. Big Blue Healthcare*, 480 F.Supp.3d 1207 (2020); *Sherod v. Comp. Healthcare Mgmt. Servs.*, No. 2:20-cv-01198, 2020 WL 6140474 (W.D.Pa. Oct. 16, 2020). Some courts erroneously concluded that complete preemption does not apply if the federal statute at issue provides an “administrative” remedy. *See Dupervil, supra*; *McCalebb v. AG Lynwood*, No. 2:20-cv-09746, 2021 WL 911951 (C.D.Cal. Mar. 1, 2021). Other courts erroneously reasoned that the PREP Act does not trigger complete preemption simply because it does not provide a substantively identical federal claim to replace the plaintiff’s preempted state law negligence claim. *Compare Sherod* at 5, *Dupervil*, and *McCalebb with Beneficial*, 539 U.S. at 8; *Anderson v. Elec. Data Sys. Corp.*, 11 F.3d 1311, 1314 (5th Cir 1994); and *Cannon v. Group Health Serv. of Oklahoma, Inc.*, 77 F.3d 1270, 1274 (10th Cir. 1996). *See also LaBuhn v. Bulkmatic Transp. Co.*, 644 F. Supp. 942, 948 (N.D. Ill. 1986) (“As is typical in these preemption cases, a removing defendant tows the case into the federal harbor only to try to sink it once it is in port.”), *aff'd*, 865 F.2d 119 (7th Cir. 1988). Several courts also improperly declined to afford deference to Advisory Opinion 21-01 or the

Fourth Amendment to the Declaration, *Dupervil*, 516 F. Supp. 3d 238; *Stone v. Long Beach Healthcare Ctr.*, No. 2:21-cv-00326, 2021 WL 1163572 (C.D.Cal. Mar. 26, 2021).

28. To date, four appellate courts have considered the issue and affirmed remand of cases removed under the PREP Act based on complete preemption. *See Maglioli v. Alliance HC Holdings*, 16 F.4th 393 (3d Cir. 2022); *Saldana v. Glenhaven Healthcare*, 27 F.4th 679 (9th Cir. 2022); *Mitchell v. Advanced HCS*, 28 F.4th 580 (5th Cir. 2022); *Martin v. Petersen Health Operations, LLC*, 37 F.4th 1210 (7th Cir. 2022). However, each of these decisions makes one or more of the same errors as set forth above. Further, each of these cases involved allegations of improper infection control, unlike this claim that an individual passed away from a COVID-19 vaccine.

29. At this juncture, the Eighth Circuit has not passed on the issue of whether claims falling within the broad preemptive scope of the PREP Act may be removed.

30. Accordingly, notwithstanding the holdings of district courts and other circuit courts to the contrary, and in the absence of any Eighth Circuit authority to the contrary, Defendant submits that the PREP Act meets both criteria for “complete preemption.” It expressly preempts a wide array of state law tort claims. It also provides an exclusive federal cause of action for any claim preempted. Therefore, federal question jurisdiction exists over any claim falling under the preemptive purview of the PREP Act.

ii. Any Claim Involving the Interpretation of the PREP Act is Removable Under the “Substantial Federal Question” Because HHS has Expressly Declared that the Application of the PREP Act is a “Substantial Federal Question”

31. Removal is also proper because Plaintiff’s Complaint presents an “substantial federal question.” *See Gunn v. Minton*, 568 U.S. 251, 258 (2013), *citing Grable & Sons Metal Prods. v. Darue Engineering & Mfg.*, 545 U.S. 308, 314 (2005).

32. In *Grable*, the Supreme Court set forth a two-step process for determining whether such a claim is removable: First, the state law claim must necessarily raise a federal issue, actually disputed and substantial. Second, federal courts must be able to entertain the state law claims, “without disturbing a congressionally approved balance of state and federal judicial responsibilities.” *Id.* at 314. The Court explained:

[I]n certain cases federal-question jurisdiction will lie over state-law claims that implicate significant federal issues. The doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.

Id. at 312. (citations omitted).

33. On December 9, 2020 HHS amended the Declaration to expressly provide that the PREP Act triggered the “substantial federal question” doctrine under *Grable*. 85 Fed. Reg. 79190 (Dec. 9, 2020). In Section XI, the Secretary formally declares:

COVID-19 is a global challenge that requires a whole-of-nation response. **There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.** The world is facing an unprecedented pandemic. To effectively respond, there **must be a more consistent pathway** for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, **there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of [*Grable*], in having a uniform interpretation of the PREP Act.** Under the PREP Act, the sole exception to the immunity from suit and liability of covered persons under the PREP Act is an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct by such covered person. In all other cases, an injured party's exclusive remedy is an administrative remedy under section 319F-4 of the PHS Act. **Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations.**

85 Fed. Reg. at 79197-98 (emphasis supplied), *citing* 42 U.S.C. § 247d-6d(b)(7).

34. This statement shows the Secretary intended for removal jurisdiction to extend to any claim that involves the “interpretation of the PREP Act,” in order to ensure a more uniform application of a statute that was integral to the Secretary’s response to the COVID-19 pandemic. **Because the PREP Act provides immunity from suit, this means that adjudication on the issue of applicability should be completed by the federal courts and not state court for purposes of uniformity.**

35. Notably, under the PREP Act, the language of this Declaration is to be conclusive on all issues regarding the invocation of the Act. *See* 42 U.S.C. § 247d-6d(b)(7) (“No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.”). At the very least, however, Section XI should be afforded *Chevron* controlling weight because it is an agency’s interpretation of the very statute it is charged with administering, because Congress has not spoken expressly on the issue, because it involves an area of knowledge within the expertise of the Secretary, and because it the Secretary’s delegated authority to lead the nation’s response to the COVID-19 pandemic. *See, e.g., Cuozzo Speed Tech., LLC v. Lee*, 136 S.Ct 2131, 2142 (2016) (“where a statute leaves a ‘gap’ or is ‘ambigu[ous],’ we typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute.”) *citing Mead Corp.*, 533 U.S. at 229; *Chevron*, 467 U.S. at 843.

36. Finally, the Secretary revisited the issue of removal jurisdiction under the *Grable* doctrine in Advisory Opinion 21-01, and reinforced the plain meaning of Section XI of the forth amendment to the Declaration. Specifically, Advisory Opinion 21-01 states:

In addition to complete preemption as the basis for article III jurisdiction and removal, ... **ordaining the metes and bounds of PREP Act**

protection in the context of a national health emergency necessarily means that the case belongs in federal court.

* * *

[T]he secretarial determination [made in the forth amendment to the Declaration] provides the underlying basis for invoking the *Grable* doctrine with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure. Once invoked, the court retains the case to decide whether the immunity and preemption provisions apply; if they do not apply, then the court would try the case as it would a diversity case. If the court finds, though, that the PREP Act applies, it would dismiss the case or if death or serious physical injury proximately caused by willful misconduct is alleged, transfer it to the District Court for the District of Columbia.

Id., 4-5 (emphasis supplied) citing *Grable, supra*; 85 Fed. Reg. at 79197; 42 U.S.C. § 247d-6d(b)(7).

37. Therefore, any claim that implicates the PREP Act is removable under the fourth amendment to the Declaration and the subsequent authority issued by HHS, both of which expressly invoke the “substantial federal question” doctrine of *Grable*.

iii. Plaintiff’s Claim Falls Under the PREP Act Because it Relates to the Administration and Use of Covered Countermeasures by a Covered Person

38. Under the PREP Act, there is preemption of any state law cause of action against a covered person that asserts “claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure” if the Secretary of HHS issues a declaration to that effect. 42 U.S.C. § 247d-6d(a)(1). In response to COVID-19, the Secretary of HHS issued the Declaration, which provided immunity under the PREP Act to any “covered person” who engaged in any “recommended activities,” including the “distribution, administration, and use” of “covered countermeasures.” 85 Fed. Reg. 15201.

39. Here, the gravamen of Plaintiff’s claim is that Defendant improperly administered the Moderna COVID-19 vaccine to Decedent. As set forth below, because such a claim

necessarily “relat[es] to” and “aris[es] out of” the “administration” or “use” of a “covered countermeasures,” by “covered persons,” it falls under the preemptive scope of the PREP Act and triggers removal jurisdiction.

a. Defendant is a “Covered Person” under the PREP Act

40. The PREP Act provides immunity to “covered persons.” 42 U.S.C. § 247d-6d(i)(2). Under the Declaration, this includes “‘program planners,’ ‘qualified persons,’ and their officials, agents, and employees”; and any person “authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction ... to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors.” 85 Fed. Reg. at 15198, 15201-02.

41. The phrase “qualified person” has a broad definition that includes any “licensed health professional or other individual who is authorized to prescribe, administer, or dispense [covered] countermeasures under [applicable state law].” 42 U.S.C. § 247d-6d(i)(8).

42. The phrase “program planner” is broadly defined as a person or entity who:

supervised or **administered a program with respect to the administration, dispensing, distribution, provision, or use** of a security countermeasure or a qualified pandemic or epidemic product, **including a person who has established requirements**, provided policy guidance, or supplied technical or scientific advice or assistance **or provides a facility to administer or use a covered countermeasure** in accordance with [the Secretary’s declaration].

42 U.S.C. § 247d-6d(i)(6) (emphasis supplied).

43. Notably, in an opinion letter dated August 14, 2020, the General Counsel to the Secretary of HHS explained that a nursing home or senior living communities would meet the definition of “program planner” if it “supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including by ‘provid[ing] a facility to administer or use

a Covered Countermeasure in accordance with' the Declaration.” See Charrow, Robert, Letter to Thomas Barker (Aug. 14, 2020) (**Exhibit I**). Further, such facilities would also be “qualified persons” when authorized under Federal, State, or local law to engage in the countermeasure activities at issue. *Id.* at n.3.

44. Finally, the phrase “person,” which is used repeatedly, includes individuals and business entities. 42 U.S.C. § 247d-6d(i)(5).

45. Here, there should be no debate that the Hillcrest Defendants are “covered persons” under the PREP Act. Plaintiff expressly alleges that these defendants owned, operated, managed, or provided consulting services to the subject skilled nursing facility. **Exhibit A**, at ¶ 5(c), (d), ¶ 6(c), (d), ¶ 7(c), (d). Accordingly, said Defendants are both “program planners” and “qualified persons.”

46. Further, not only are each of the named-defendants “covered persons,” but so are all of their officials, agents, and employees. See § 247d-6d(i)(2)(B)(v); 85 Fed. Reg. 15198, 15201-02.

47. Therefore, the Hillcrest Defendants are “covered persons” within the meaning of the PREP Act and the Declaration.

b. Plaintiff’s Claim Relates to a “Covered Countermeasure” under the PREP Act

48. As set forth in the Declaration, the term “covered countermeasure” is defined as follows:

[(1)] ***any*** antiviral, ***any*** other drug, ***any*** biologic, ***any*** diagnostic, ***any*** respiratory protective device, ***any other device***, or any vaccine, ***used***

a. ***to treat, diagnose, cure, prevent, or mitigate COVID-19***, or the transmission of SARS-CoV-2 or a virus mutating therefrom, ***or***

- b. ***to limit the harm that COVID-19***, or the transmission of SARS-CoV-2 or a virus mutating therefrom, ***might otherwise cause***; or

(2) any device used in the administration of any such product, and all components and constituent materials of any such product.

* * *

[provided the product can also be classified as one or more of the following:] “qualified pandemic or epidemic products,” or “security countermeasures,” or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act, or any respiratory protective device approved by NIOSH under 42 CFR part 84 ...

85 Fed. Reg. at 35102 (emphasis supplied); *see also* 42 U.S.C. § 247d-6d(i).

49. It is a matter of public record that, on December 18, 2020, the FDA granted emergency use authorization for the Moderna COVID-19 vaccine. *See* FDA, Letter to ModernaTX, Inc. (Dec. 18, 2020) (**Exhibit J**).

50. Therefore, the Moderna vaccine is a “covered countermeasure” under the PREP Act.

c. Plaintiff’s Claim Relates to the “Administration” and “Use” of a “Covered Countermeasure” under the PREP Act

51. Plaintiff’s claim stems from the alleged administration and used of a “covered countermeasure” against COVID-19. It therefore falls under the purview of the PREP Act because it “relates to” and “arises out of” the “administration” and use of a covered countermeasure.

52. The PREP Act applies to any claim for injury that is “caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure” 42 U.S.C. § 247d-6d(a)(1). The Declaration, in turn, provides PREP Act immunity for all “recommended activities,” which include the “use” or “administration” of covered countermeasures. 85 Fed. Reg. at 15201.

53. The phrase “use” is not defined under the PREP Act. However, the phrase “administration” is actually defined within the Declaration itself, and that definition clearly extends *beyond* the physical provision of countermeasures to recipients:

Administration ... means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

85 Fed. Reg. 15202 (emphasis supplied). In the Preamble of the Declaration, the Secretary explains that this definition of “administration” is interpreted, in relevant part, as:

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging ... negligence by a health care provider in prescribing the wrong dose, absent willful misconduct ...

85 Fed. Reg. 15200 (emphasis supplied).

54. Every material allegation of the complaint either “relat[es] to,” or “aris[es] out of” the fact that the Decedent allegedly received the Moderna vaccine as a resident of Hillcrest. *See Exhibit A*, ¶¶ 5(f), 6(g), 7(h), 20, 24-53, 61. Plaintiff also expressly alleges that Decedent’s death resulted from his receipt of the vaccine. *See id.* at ¶¶ 48-53. Further, since this claim is for personal injury, it is a “claim for loss” within the meaning of the statute. *See* § 247d-6d(a)(2)(A) (defining “loss”).

55. Therefore, Plaintiff asserts a “claim for loss” relating to the administration of a covered countermeasure, and is limited to the exclusive federal cause of action for “willful misconduct” provided by the PREP Act. While Plaintiff takes issue with *how* the vaccine was administered, that is exactly the type of claim the PREP Act was designed to prevent. *See* 85 Fed. Reg. 15198, 15199-200.

B. FEDERAL OFFICER JURISDICTION UNDER 28 U.S.C. § 1442

56. Removal is permitted under 28 U.S.C. § 1442(a)(1) when a defendant is sued for actions taken at the direction of a Federal Officer. *See In re Commonwealth's Motion to Appoint Counsel Against or Directed to Def Ass'n of Phila.*, 790 F.3d 457 (3rd Cir. 2015). This is to be broadly construed in favor of a federal forum. *Id.* at 467.

57. Federal officer jurisdiction exists under § 1442(a)(1) if the following conditions are met: (1) the defendant it is a “person” within the meaning of the statute; (2) the claim is based upon defendant’s conduct while “acting under” a federal officer; (3) a causal nexus exists between the claims and the conduct performed; and (4) a colorable federal defense is raised. *Jefferson County, Ala. v. Acker*, 527 US 423, 431 (1999); *In re Commonwealth*, 790 F.3d at 467 (3rd Cir. 2015).

58. The first requirement is met because Defendants are all either individuals or business entities, and thus meet the definition of “person.” *See In re Commonwealth*, 790 F.3d at 467-68 (3rd Cir. 2015); 1 U.S.C. § 1.

59. The “acting under” requirement is to be “liberally construe[d]” to cover actions that involve “an effort to assist, or to help carry out, the federal supervisor’s duties or tasks.” *Ruppel v. CBS Corp.*, 701 F.3d 1176, 1181 (7th Cir. 2012), *quoting Watson v. Philip Morris Cos., Inc.*, 551 U.S. 142 (2007); *see also In re Commonwealth*, 790 F.3d at 468 (2015). To satisfy the “acting under” requirement, “a private person’s actions ‘must involve an effort to assist, or to help carry out, the duties or tasks of the federal superior.’” *Watson*, 551 U.S. at 152.

60. Federal courts “have explicitly rejected the notion that a defendant could only be “acting under” a federal officer if the complained-of conduct was done at the specific behest of the federal officer or agency.” *Papp v. Fore-Kast Sales Co., Inc.*, 842 F.3d 805, 813 (3d Cir.

2016). Instead, a specific instruction from a federal officer, or a detailed regulation to compel specific conduct satisfies the “acting under” requirement. *See Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d 387 (5th Cir. 1998). “The hurdle erected by this requirement is quite low.” *Isaacson v. Dow Chem. Co.*, 517 F.3d 129, 137 (2d Cir. 2008).

61. Also, unlike the tobacco industry at issue in *Watson v. Philip Morris Cos., Inc.*, the public health sector is a “critical infrastructure” within which the Federal Government works with owners and operators of healthcare-related facilities to promote national safety, especially during times of public health emergency. *See* Presidential Policy Directive—Critical Infrastructure Security and Resilience, The White House (Feb. 12, 2013)²; *see also Fields v. Brown*, No. 6:20-cv-00475, 2021 WL 510620, *3 (ED Tex. Feb. 11, 2021) (finding a defendant's designation as critical infrastructure sufficient for federal officer jurisdiction where the defendant was, *inter alia*, closely monitored by federal agencies.).

62. In response to the COVID-19 pandemic, many federal officers and agencies issued detailed, regularly evolving guidance and regulations in order to facilitate a “whole of nation” response to the declared public health emergency.³ The Centers for Medicare and

² Available at: <https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil>.

³ *See* CMS, Press Release “CMS Prepares Nation’s Healthcare Facilities for Coronavirus Threat” (February 6, 2020) (available at <https://www.cms.gov/newsroom/press-releases/cms-prepares-nations-healthcare-facilities-coronavirus-threat>); CMS Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (February 1, 2020) (available at <https://emergency.cdc.gov/han/HAN00427.asp>); CMS Guidance for Infection Control and Prevention Concerning Coronavirus (COVID-19): FAQ’s and Considerations for Patient Triage, Placement and Hospital Discharge (March 4, 2020) (available at <https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2>); CMS Guidance for use of Certain Industrial Respirators by Health Care Personnel (March 10, 2020) (available at <https://www.cms.gov/files/document/qso-20-17-all.pdf>); HHS, Emergency Use Declaration, Federal Register/ Vol. 85, No. 47 (March 10, 2020) (available at <https://www.govinfo.gov/content/pkg/FR-2020-03-10/pdf/2020-04823.pdf>); CMS Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes (Revised) (March 13, 2020) (available at <https://www.cms.gov/files/document/qso-20-14-nh-revised.pdf>); CMS, COVID-19 Long-Term Care Facility Guidance (April 2, 2020) (available at <https://www.cms.gov/files/document/4220-covid-19-long-term-care-facility-guidance.pdf>); CMS, Press Release “Trump Administration Announces New Nursing Homes COVID-19 Transparency Effort” (April 19, 2020) (available at <https://www.cms.gov/newsroom/press-releases/trump-administration-announces-new-nursing-homes-covid-19-transparency-effort>).

Medicaid Services (“CMS”) issued various protocols for COVID-19 testing, prioritization and allocation of PPE, experimental treatments for COVID-19, and infection prevention and control standards.⁴ Similarly, the Centers for Disease Control (“CDC”) issued a substantial amount of guidance aimed at curbing the spread of COVID-19 throughout the nation.⁵ Both CDC and CMS are subsidiaries of HHS, which is authorized under the Public Health Service Act to lead the nation’s response to a public health emergency. *See* 42 U.S.C. § 247d, *et seq.* Accordingly, these guidelines created “strong government intervention” which went beyond the “mere auspices of federal direction” due to the unprecedented pandemic. *See Fung v. Abex Corp.*, 816 F. Supp. 569, 572 (N. D. Cal. 1992).

63. Here, as members of the public health sector, Defendants were the primary targets of the guidance and regulations issued by CDC and CMS. Accordingly, they were “acting under” these federal agencies by taking efforts to comply with the same, thereby “assisting” CDC and CMS “whole of nation” response.

64. In addition, the Defendant facility is a nursing home subject to CMS regulation under 42 C.F.R. Part 483. Accordingly, as of May 8, 2020, Defendants were directed to implement a system of identifying individuals with suspected or confirmed cases of COVID-19, and to submit periodic reports to the Secretary of HHS regarding the rates of COVID-19 infection and related details. *See* 42 C.F.R. 483.80 (81 Fed. Reg. 68868, Oct. 4, 2016, *as amended at* 85 Fed. Reg. 27627, May 8, 2020; 85 Fed. Reg. 54873, Sept. 2, 2020; 86 Fed. Reg. 26335, May 13, 2021).

⁴ *See* CMS, Emergency Preparedness & Response Operations, Current Emergencies, *available at*: <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>.

⁵ *See* CDC, Guidance Documents, *available at*: <https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Adesc>.

65. Further, Defendant was a participant in the CDC COVID-19 Vaccination Program. Pursuant to that Agreement, Defendant was authorized to administer COVID-19 vaccines initially purchased by the United States government.

66. With respect to the “causal nexus” requirement, a defendant must “demonstrate that the acts for which they are being sued . . . occurred because of what they were asked to do by the Government.” *Isaacson*, 517 F.3d at 137 (2d Cir. 2008). In determining whether that causal connection exists, a court must take into account the defendant’s theory of the case. *Id.*

67. Here, as set forth on the face of the Complaint, Plaintiff’s claim is causally related to Defendants’ response to the COVID-19 pandemic, and more specifically their alleged administration of the Moderna COVID-19 vaccine. Those actions were undeniably the very subject of the large number of detailed guidance and regulations issued by the federal government that are addressed above. Therefore, the requisite causal connection is present.

68. Finally, with respect to the “federal defense” requirement, the defense must be “colorable” and need not be “clearly sustainable” because the purpose for the removal statute is to ensure that the validity of the defense may be decided in federal court. *Willingham v. Morgan*, 395 U.S. 402, 407 (1969). Here, for the reasons set forth above, Defendants assert that they have immunity from suit under the PREP Act, a federal statute. Therefore, this final requirement is plainly satisfied.

69. Therefore, this court has federal officer jurisdiction pursuant to 28 U.S.C. § 1442, and removal is proper.

C. SUPPLEMENTAL JURISDICTION UNDER 28 U.S.C. § 1367

70. When a case is removed based on federal question jurisdiction or federal officer jurisdiction, under 28 U.S.C. § 1367, a district court has supplemental jurisdiction “over all other claims that are so related ... that they form part of the same case or controversy.”

71. Here, all of the conduct alleged in the Complaint arises from the same set of transactions and occurrences. Therefore, to the extent that any cause of action contained within the Complaint does not fall within the federal question jurisdiction or the federal officer jurisdiction of the District Court as set forth above, Defendants request that the Court exercise its supplemental jurisdiction over such residual causes of action pursuant to 28 U.S.C. § 1367.

72. Therefore, federal officer jurisdiction exists over the allegations in the Complaint because they relate to Defendants’ actions taken at the direction of a Federal Officer.

D. EXCLUSIVE ORIGINAL JURISDICTION UNDER 42 U.S.C. § 247d-6d(e)(1)

73. The Removing Defendants maintain that Plaintiff’s pleadings do not assert any legally cognizable cause of action because the claim pleaded relates to and arises out of his “administration” and “use” of “covered countermeasures” against COVID-19; and that, therefore, the claim falls under the preemptive purview of the PREP Act.

74. However, said Defendants further assert in the alternative that, to the extent Plaintiff’s pleadings are construed to assert any viable cause of action, the sole cause of action they could assert would be a claim for “willful misconduct” under the PREP Act. *See* 42 U.S.C. § 247d-6d(d)(1).

75. Under the PREP Act, the District Court for the District of Columbia has exclusive jurisdiction for claims of “willful misconduct” brought under 42 U.S.C. § 247d-6d(e)(1), which

states that “[a]ny action under [42 U.S.C. § 247d-6d(d)] shall be filed and maintained only in the United States District Court for the District of Columbia.”

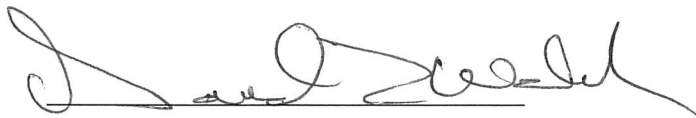
76. Therefore, to the extent that the Complaint asserts any cognizable cause of action, that cause of action raises a federal question over which the District Court for the District of Columbia has exclusive jurisdiction pursuant to an act of congress, and this matter is removable under § 247d-6d(e)(1).

77. Notwithstanding, said Removing Defendants reserve all rights to contest the validity of any purported claim for “willful misconduct,” including all procedural requirements, pleading requirements, and venue requirements set forth in § 247d-6d(e). Upon removal, said Defendants intend to move for dismissal under the same and reserves the right to request transfer to the District Court for the District of Columbia.

WHEREFORE, having shown that this case is properly removable, Defendant provides notice pursuant to 28 U.S.C. § 1441, 1442, and 1446, that the Action pending in the District Court of Sarpy County, Nebraska is removed to the United States District Court for the District of Nebraska, and respectfully requests that this Court exercise jurisdiction over this case.

Respectfully submitted this 20 day of July, 2022.

RED OAK HEALTH SERVICES, INC. d/b/a HILLCREST
HEALTH & REHAB; HILLCREST HEALTH SYSTEMS,
INC. d/b/a HILLCREST HEALTH SERVICES, and
HILLCREST OPERATING VENTURES, LLC,
Defendants



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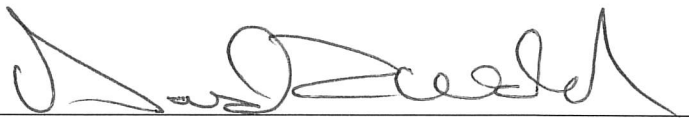
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CERTIFICATE OF SERVICE

The undersigned hereby affirms and certifies that a copy of the foregoing document was deposited in the United States Mail this 20 day of July, 2022 to:

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